Barriers in clinical research in EU: (rare disease) investigator perspective

Results of ERICA *(European Rare Disease Research Coordination and Support Joint Action)* WP4 Survey 2023:

- Challenges in building relationships with regulatory agencies/authorities

		Answers	Ratio
Very low		4	2.29 %
Low		22	12.57 %
Neutral		54	30.86 %
High		61	34.86 %
Very high		34	19.43 %

- Challenges in conducting clinical research that complies with regulatory requirements

		Answers	Ratio
Very low		7	4 %
Low		32	18.29 %
Neutral		47	26.86 %
High		59	33.71 %
Very high		30	17.14 %

Opportunities for clinical trialing in EU: investigator perspective

- Consolidation of EU pharmaceutical markets (re-imbursement/tenders)
- Harmonization of MS interpretation of GDPR and successive legislation
- Harmonization and standardization of part II CTIS (i.e. ICFs should be identical)
  - PIF EU standard/ reference texts (patient rights) not needed to be incorporated/simplified

- Harmonization of CTA contracts and regulations
  - IE non-EU governing law forbidden
  - Penalties forbidden
  - Liability cap
  - Benchmark for Medical personnel (ie French CTA, Dutch CGR)

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